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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,460	04/01/2002	Willem Johan Van Der Giessen	2005-1001	9285

466 7590 11/14/2007  
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ARLINGTON, VA 22202

EXAMINER
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AZPURU, CARLOS A

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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11/14/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/089,460

**Applicant(s)**

VAN DER GIESSEN ET AL.

**Examiner**

Carlos A. Azpuru

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-6, 8- 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-6, 8- 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Receipt is acknowledged of the amendment filed 08/23/2007.

The rejection under 35 USC 112, second paragraph is hereby withdrawn.

The following rejection is maintained in this action:

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-6, 8- 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider et al (Journal of Vascular Surgery).

Schneider et al disclose vascular grafts on which a coating of heparin sulfate, laminin and collagen may be added (see abstract). This collagen is collagen type II and IV (see page 649, column 1, line 3). The composition may also contain nidogen (page 649, column 1, line 6) and bovine fibroblast growth factor (page 649, column 1, line 1). Nidogen and entactin are the same protein. Further, the reference specifically recited

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coating of the vascular grafts with extracellular matrix. Along with the components cited above, vitronectin and fibronectin are components of the extracellular matrix. Schneider further washes the extracellular matrix with a solution containing penicillin and streptomycin, adding antibiotics to the coating (see Materials and Methods, page 650). While the reference does not set out the percentages of each component, it is clear that all claimed components of the coating are present. As such, it would have been well within the skill of the ordinary practitioner to claim the instant intraluminal device by modifying the weight percentages of each through routine experimentation, and further, expect similar therapeutic results from the use of such a coating on an intraluminal device as set out by Schneider et al. Given that extracellular matrix already has these components present, applicant would need to show that the amounts set out in the claims would not be present in extracellular matrix, or that they are so unexpectedly different that they would teach away from the reference. As such, it is deemed that the instant claims would have been obvious to one of ordinary skill in the art at the time of invention given the teachings of Schneider et al.

### ***Response to Arguments***

Applicant's arguments filed 08/23/2007 have been fully considered but they are not persuasive.

With regard to the rejection under 35 USC 103(a), applicant correctly argues that the article by Schneider et al does not disclose or suggest the instantly claimed percentages of the claimed substituents. However, each of the constituents is taught by

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the reference. Each of these is in turn art recognized, and has art recognized physiological and therapeutic properties. In the previous action it was pointed out, that optimization of the weight percentages of each is a skill within that of any ordinary practitioner, and for the same art recognized purpose of finding an effective coating for an intraluminal device. As such, the motivation to improve the coating set out by Schneider by modifying the percentages of each known component would have been obvious to any ordinary practitioner.

Applicant further argues that while claim 6 sets out that antibiotic is added to the coating, Schnieder et al uses antibiotic to wash the extracellular matrix and does not suggest presence in the final coating. NO removal step is described in the reference however, and applicant would be required to show that no antibiotic is present in the final coating product through comparative data. The rejection under 35 USC 103(a) over Schneider et al is therefore maintained.

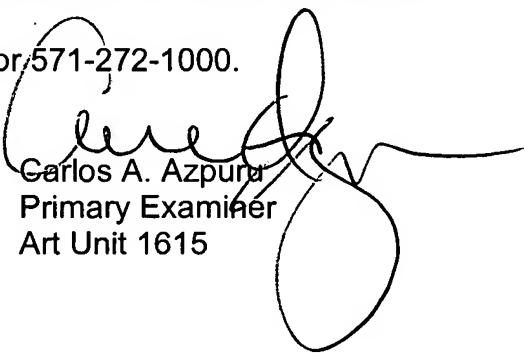
Lastly, applicant refers to the citation in the Encyclopedia of Molecular Medicine and its publication date. However, the citation was merely made as background art in teaching the composition of extracellular matrix substituents. This was not meant as a prior art reference to be used in a rejection.

Claim 7 is objected to as dependent upon a rejected base claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Carlos A. Azpuru  
Primary Examiner  
Art Unit 1615

caz